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EXAMINER	
TOWA, RENE T	
ART UNIT	**PAPER NUMBER**
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,540	LI ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,13,19 and 45-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,13,19 and 45-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed November 13, 2007. Claims 1, 8, 13, 16, 19 & 45-76 are pending. Claims 1, 13, 19, 45, 52-54, 60 & 63 have been amended. Claims 2-7, 9-12, 14-15, 17-18 & 20-44 have been cancelled. New claims 66-76 have been added.

Claim Objections

2. The objections are withdrawn due to amendments.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

"A system" hereinafter is intended to mean "an apparatus" and/or "a method."

4. **Claims 1, 13, 19, 45-51, 54-57, 62-66, 68, 70, 72 & 74-75** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo (US 6,623,698) in view of Voyiazis et al. (US 2004/0147906), Giuliani et al. (US 5,476,384), Murayama (US Re. 36,699), and Doneen et al. (US 6,102,872).

In regards to claims 1, 13, 19, 45-51, 55-57, 62-66, 68, 70, 72 & 74-75, Kuo *discloses a system for making a physiological test comprising:*

a biometric device for collecting and analyzing the oral fluid;

an oral platform or device 6;

a matrix of sensors (138, 140) mounted on or in the platform 6 for making medical diagnoses;

a stick 2 connected to the platform 6 to serve as a handle and electrical conduit to and from the matrix of sensors (138, 140) and the platform 6, where the platform, matrix of sensors (138, 140), and stick are mechanically combined together; and

a base unit 2 for providing a medical diagnosis related to the oral sample (see figs. 1a, 4a-c & 5a-c; column 6/lines 32-54 & 60-67; column 7/lines 1-20; column 8/lines 53-63; column 9/lines 32-50; column 10/lines 25-31; column 14/lines 37-41; column 16/lines 40-53);

wherein the biometric device as controlled by the base unit 2 performs a colorimetric or electrochemical bioassay (see column 16/lines 47-53) that monitors physical phenomena including oral activity;

wherein the system further comprises means for delivering drugs (see fig. 6A; column 10/lines 25-27; column 37-41);

wherein the system also comprises means for inducing a physical change in a patient (see column 9/lines 11-12);

wherein the biometric device performs diagnostics (see abstract);

wherein the biometric device is configured for sustained data collection of oral fluid with patient acceptance and simplicity of application;

wherein the biometric device is configured to test for the presence of a secondary agent (i.e. a blood glucose level, which corresponds to a correct dosage of insulin for a diabetes patient) (see column 6/lines 32-44);

wherein the biometric device is capable of being used to detect analytes related to tooth decay or periodontal disease (i.e. by providing the appropriate reagent cartridge) (see column 6/lines 11-20 & 39-44).

The limitation "stick" is herein construed as "something slender and often cylindrical" as per is Webster's II New Riverside University Dictionary (1994).

Kuo discloses a system, as described above, that fails to explicitly teach a microchip, interchangeable base unit, a stick capable of serving as a fluidic conduit, or a combination of an oral platform, biometric device and handle that comprises a lollipop-like assembly.

*However, **Voyiazis et al.** teach a system for making a physiological test and/or delivery of drugs comprising a microchip mounted in a platform for making medical diagnoses and/or selectively providing controlled delivery of drugs, the microchip comprising at least one of a lab-on-a-chip system 290 (see abstract; see figs. 5-6; par 0009, 0013-0014, 0016, 0018, 0021 & 0060-0063).*

***Giuliani et al.** disclose a system comprising a stick 13 capable of serving as a fluidic conduit via means 32 for delivering drugs (see figs. 1 & 3; column 2/lines 34-46; column 3/lines 31-49; column 3/line 63 to column 4/line 1; column 6/lines 13-26; see abstract); wherein the means for delivering drugs is controlled to provide timed drug delivery (see column 5/lines 29-44).*

***Murayama** discloses a system comprising an active cooperative base unit 14 capable of selective and interchangeable communication with a plurality of oral devices*

(see figs. 2A-B & 4A-B; column 4/lines 16-26; column 5/lines 20-32; column 6/lines 64-67; column 7/lines 1-3).

Doneen et al. *disclose a system for making a physiological test comprising a biometric device, an oral platform or device 10', and a stick or handle 26 such that the combination of the oral platform 10', biometric device and handle 26 comprises a lollipop-like shell assembly; (see figs. 1-3; column 2/lines 33-47; column 3/lines 44-56; column 5/lines 35-44; column 6/lines 17-21; column 7/lines 31-33 & 40-54); wherein the system further includes a filter 12 and preservation means 16 (i.e. citric acid) for preserving the saliva, where the saliva passes through the filter and is combined with preservatives by the preservation means 16 during collection (see column 4/lines 54-64; column 5/lines 9-16, 21-24, 35-38 & 44-50).*

In regards to claims 1, 13, 19, 45-48, 50, 56, 62-65, 68 & 74:

Since both Kuo and Voyiazis et al. teach device for making medical diagnoses of body fluids in the mouth of a patient, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify a system similar to that of Kuo to include a microchip comprising a lab-on-a-chip system similar to that of Voyiazis et al. in order to achieve a system that autonomously performs and report the analysis of the body fluids in vivo.

Since Kuo and Giuliani et al. teach electronic powered brushes with dispensing means (see Kuo, column 10/lines 25-27 & 36-39; column 14/lines 37-41; see Giuliani et al., column 2/lines 34-46), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as

modified by Voyiazis et al. with a stick serving as a fluidic conduit similar to that of Giuliani et al. since such a modification will serve the same purpose of dispensing fluid (see Giuliani et al., column 3/lines 63 to column 4/line 1).

Kuo, Giuliani et al., and Murayama all disclose electronic powered brushes; moreover, Kuo teaches that, as an oral device, the bristle elements can be replaced by a gum massaging element, a dental floss, a toothpick, a tongue scraper or element used for dental or medical functions (see column 16/lines 39-43). As such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar Kuo as modified by Voyiazis et al. and Giuliani et al., above, with an interchangeable base unit similar to that of Murayama in order to preserve the electrical components of the system while replacing the other elements used for dental functions so as to thereby avoid the spread of an infection.

Since Doneen et al. and Kuo as modified by Voyiazis et al., Giuliani et al. and Murayama, above, teach a system for making a physiological oral test that includes an oral platform, a biometric device and handle as an integral element, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al. and Murayama with an oral platform, a biometric device and handle that are integral in a lollipop-like shell assembly similar to that of Doneen et al. in order to encourage children to keep the testing device in their mouths and reduce the anxiety associated with oral examinations.

In regards to claims 49:

Doneen et al. and Kuo as modified by Voyiazis et al., Giuliani et al. and Murayama, teach a system for making a physiological oral test that includes an oral platform, a biometric device and handle as an integral element, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al. and Murayama with a filter similar to that of Doneen et al. in order to obtain an ultrafiltered, uniform, non-viscous sample required for accurate measurement (see Doneen et al., column 5/lines 9-16).

In regards to claim 51:

Since Kuo and Giuliani et al. teach electronic powered brushes with dispensing means (see Kuo, column 10/lines 25-27 & 36-39; column 14/lines 37-41; see Giuliani et al., column 2/lines 34-46), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo with a timed drug delivery means similar to that of Giuliani et al. in order to controllably deliver the drug so that no drug is dispensed when the oral device is not in use.

In regards to claim 55:

Since Doneen et al. suggest a single use lollipop-type oral device to thereby avoid the spread of an infection (see column 3/lines 59-61), Kuo suggests a multiple bioassay system (see column 6/lines 11-20 & 39-44), and Murayama discloses an interchangeable power or base unit, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with a

plurality of single-use lollipop-type oral device to conduct multiple bioassays while avoiding the spread of an infection.

In regards to claim 57:

Since Doneen et al. and Kuo teach a means for inducing a physical change in a patient (i.e. saliva-stimulation) (see Doneen et al., column 5/lines 35-38 & abstract; see Kuo, column 9/lines 10-12 & abstract), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with a means, as claimed, in order to stimulate saliva production.

In regards to claims 66, 70, 72 & 75:

Since Kuo and Doneen teach a means for inducing saliva production a patient (see Doneen et al., column 5/lines 35-38 & abstract; see Kuo, column 9/lines 10-12 & abstract), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al., above, to include an edible candy shell, as claimed, in order to stimulate salivation in a patient without raising a suspicion of the testing by relying on a stimulant whose taste is preferred by most patients (i.e. especially children).

5. ***Claims 8, 16 & 60-61*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo in view of Voyiazis et al., Giuliani et al., Murayama, Doneen et al. further in view of Lundell et al. (US 6,611,780).

Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. disclose a system, as described above, that teaches all the limitations of the claim except for a cradle unit.

However, Lundell et al. disclose a system comprising a biometric device 10 including a base unit 11 that provides data processing and communication in addition to a cradle unit 12, which further produces data processing, communication and/or display; the system further comprising wireless transmission and programming of the biometric device; wherein the system further comprises an external instrument 34 capable of aiding and enhancing the utility of the system for downloading data from the biometric device, for logging or analysis, of providing power and/or control over the biometric device (see figs. 1A-B; column 1/lines 8-14 & 55-62; column 2/lines 10-31 & 50-67; column 3/lines 14-32; column 5/lines 43-48 & 56-60).

In regards to claims 8 & 16, since Lundell et al. and Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. teach a system comprising a biometric device including a base unit for providing a medical diagnosis, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with a cradle unit similar to that of Lundell et al. in order to charge the biometric device and communicate biometric data therefrom (see Lundell et al., column 2/lines 50-67).

In regards to claim 60, it would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a system similar to that of Kuo as

modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with a step similar to that of Lundell et al. in order to remotely program information into the biometric device (see Lundell et al., column 5/lines 43-48).

In regards to claim 61, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with an external instrument similar to that of Lundell et al. in order to remotely analyze user profiles in clinical situations, monitor and control use of the biometric device by particular patients, and remotely display and analyze the biometric data (see Lundell et al., column 3/lines 20-25; column 5/lines 43-48 & 56-60).

6. ***Claims 8, 16, 60-61 & 69*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo in view of Voyiazis et al., Giuliani et al., Murayama, Doneen et al. further in view of Yang et al. (US 6,536,068).

Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. disclose a system, as described above, that fails to explicitly teach a cradle unit.

However, Yang et al. disclose a system comprising a biometric device including a a cradle unit 24, which further produces data processing, communication and/or display; the system further comprising wireless transmission and programming of the biometric device; wherein the system further comprises an external instrument 34 capable of aiding and enhancing the utility of the system for downloading data from the biometric device, for logging or analysis, of providing power and/or control over the biometric device; wherein the cradle unit further provides data processing, communication and/or

display in addition to that provided by the base unit (see figs. 1-1A; col. 4, lines 52-67; col. 5, lines 1-10).

In regards to claims 8, 16 & 69, since Yang et al. and Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. teach a system comprising a biometric device including a base unit for providing a medical diagnosis, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with a cradle unit similar to that of Yang et al. in order to charge the biometric device and communicate biometric data therefrom if the data storage in the biometric device is limited or temporary.

In regards to claim 60, it would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with a step similar to that of Yang et al. in order to remotely program information into the biometric device.

In regards to claim 61, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with an external instrument similar to that of Yang et al. in order to remotely analyze user profiles in clinical situations, monitor and control use of the biometric device by particular patients, and remotely display and analyze the biometric data (see col. 5, lines 11-23).

7. ***Claims 52-54*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo in view of Voyiazis et al., Giuliani et al., Murayama, Doneen et al. further in view of Mink et al. (US 6,303,081).

Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. disclose a system, as described above, that fails to explicitly teach a stimulating coating.

However, Mink et al. disclose a system comprising a biometric device 18, an oral device (BP), and a stick D; wherein the oral device includes a coating to stimulate salivary action to aid the bioassay (see figs. 3-4; see abstract; see column 4/lines 14-24; column 17/lines 44-50).

In regards to **claim 54**, Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. disclose a system, as described above, that teaches all the limitations of the claim except for a coating. However, since Doneen et al. teach that saliva stimulation, at least in part, affects the time that oral fluid is transferred between the mouth and the biometric device (see column 6/lines 48-67), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with a saliva-stimulating coating to adjust the time that the oral fluid is transferred.

In regards to **claims 52-54**, Mink et al., Doneen et al., and Kuo as modified by Voyiazis et al., Giuliani et al. and Murayama, teach a system for making a physiological oral test that includes an oral platform, a biometric device and handle as an integral element; moreover, Mink et al., Doneen et al. and Kuo teach a step for stimulating

salivary action to thereby aid the bioassay (see Doneen et al., column 5/lines 35-38 & abstract; see Kuo, column 9/lines 10-12 & abstract; see Mink et al., column 4/lines 14-24; column 17/lines 44-50 & abstract); as such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with a coating similar to that of Mink et al. in order to stimulate to production of saliva.

8. ***Claims 58-59*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo in view of Voyiazis et al., Giuliani et al., Murayama, Doneen et al. further in view of Kawamura et al. (US 6,685,471).

Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. disclose a system, as described above, that fails to explicitly teach means for imaging tissue.

However, Kawamura et al. disclose a system comprising a biometric device 1 and an imaging device 12; wherein the imaging device is an endoscope (see fig. 4; see abstract; column 7/lines 14-50).

Since both Kawamura et al. and Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. teach an electrically powered oral device, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. with an imaging device similar to that of Kawamura

et al. in order to enable a user to observe whether or not the oral device is in the desired location in the oral cavity (see Kawamura et al., column 1/lines 43-49).

9. ***Claims 67, 71, 73 & 76*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo in view of Voyiazis et al., Giuliani et al., Murayama, Doneen et al. further in view of Lee et al. (US 6,146,103).

Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al. disclose a system, as described above, that fails to explicitly teach a microchip configured to control fluids using magnetohydrodynamic (MHD) fluidics.

However, Lee et al. disclose a system configured to control fluids using magnetohydrodynamic (MHD) fluidics (see abstract; see figs. 8-9; col. 2, lines 19-44; col. 5, lines 43-67; col. 6, lines 1-17).

Lee et al. teach an MHD system usable in medical devices for analyzing and processing biological samples, and as pumps for drug delivery (see col. 6, lines 37-47); since Voyiazis et al. teach a microchip for analyzing and processing biological samples, and as pumps for drug delivery (see par 0046 & 0062), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify a system similar to that of Kuo as modified by Voyiazis et al., Giuliani et al., Murayama and Doneen et al., to include an MHD pump in order to control the direction of flow through the microchip.

Response to Arguments

10. Applicant's arguments filed November 13, 2007 have been considered but are moot in view of the new ground(s) of rejection. However, it is worth noting that contrary

to the Applicant's arguments none of the claims are directed to an apparatus for making a physiological test and/or delivery of drugs; as such, the apparatus may be toothbrush, a tooth implant or a thermometer, etc.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RTT/